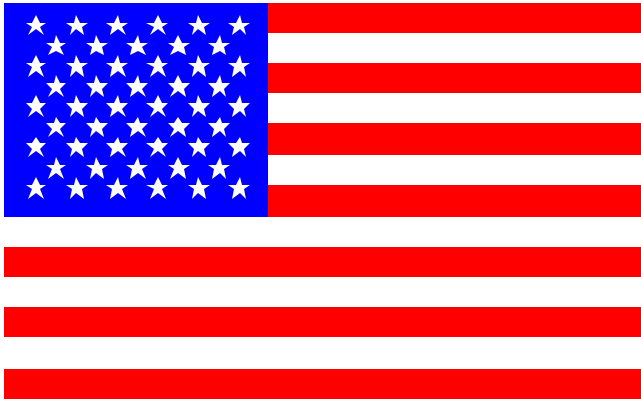


**SECOND ANNUAL REPORT OF THE
MEDICAL DEVICES ANNEX TO THE
U.S./EC MUTUAL RECOGNITION
AGREEMENT (MRA)**



December 1, 2000

INTRODUCTION

Article 7 of the Medical Device Annex to the U.S./EC Mutual Recognition Agreement (MRA) requires the Commission for the European Communities (CEC) and the government of the United States (U.S.) to prepare annual progress reports which describe the confidence building activities undertaken during each year of the confidence building period. This is the SECOND progress report, and has been prepared jointly by the U.S. Food and Drug Administration (FDA), the National Institute of Standards and Technology (NIST) and the CEC addressing the implementation of the Medical Devices Annex. It includes background on the MRA and a chronology of accomplishments. This report covers activities from December 1, 1999 to December 1, 2000.

BACKGROUND ON THE U.S./EC MUTUAL RECOGNITION AGREEMENT: THE MEDICAL DEVICES ANNEX

On June 20, 1997, the U.S. and the CEC for the European Communities (EC) concluded negotiation of the MRA, which covers a variety of product sectors including telecommunications equipment, electromagnetic compatibility, electrical safety, recreational craft, pharmaceutical good manufacturing practice (GMP) inspections, and medical devices. The aim of this agreement is to facilitate transatlantic trade while reducing costs for compliance with regulatory requirements. On May 18, 1998, the MRA was signed by representatives of the U.S. and the EC marking the start of implementation. On October 30, 1998, there was an exchange of letters between the Parties that inaugurated the confidence building period. This agreement became effective December 1, 1998. The Medical Device Annex to the MRA became effective on December 7, 1998, the effective date of the FDA final rule. The effective date initiated a three year transition period during which time both sides will engage in confidence building activities. After the three year period, the agreement would become operational as to conformity assessment bodies (CABs) for which the confidence building activities are successfully completed.

The MRA consists of a framework agreement and individual sectoral annexes. The framework agreement covers the general aspects of the implementation of the agreement as well as requirements governing CABs, such as listing, suspension and withdrawal.

The Medical Device Annex covers the exchange of quality systems evaluation reports for all medical devices and premarket evaluation reports for selected low to medium risk devices. A European CAB can conduct quality system inspections for all classes of devices and 510(k) evaluations for selected devices based on FDA requirements.

Similarly, a U.S. CAB can conduct quality system audits for all classes of devices and type-testing evaluations for selected devices based on EC requirements. In addition, an alert system will be established during the transition period and maintained thereafter, by which the Parties will notify each other when there is an immediate danger to public health. As part of that system, each Party shall notify the other Party of any medical device manufacturer problem reports, corrective actions, or recalls.

CHRONOLOGY OF ACCOMPLISHMENTS TOWARDS THE IMPLEMENTATION OF THE MEDICAL DEVICE ANNEX TO THE U.S./EC MRA

December 1, 1999-FDA completed its draft of the first MRA Annual Report, which was forwarded to the CEC.

January 5, 2000- FDA and NIST representatives met to critique dossiers submitted by 10 U.S. CAB's that included checklists and supporting conflict-of-interest and auditor qualification data. NIST provided FDA with dossiers that contained sufficient data for an in-depth review

January 20, 2000-FDA met with Mr. Robert Allen, Medical Devices Agency (MDA) United Kingdom in Rockville, Maryland and edited version six of the Implementation Plan.

January 27, 2000 – NIST sent a letter to FDA to request that FDA obtain assurances from the CEC that confidentiality will be maintained of the material submitted by U.S. CABs in response to the checklist.

February 2, 2000 – NIST and FDA representatives met with members of the American National Standards Institute and the Registrar Accreditation Board (ANSI-RAB) to discuss the status of implementation of the MDD sector of the MRA. The major items of discussion were ANSI-RAB's application process to the National Voluntary Conformity Assessment System Evaluation (NVCASE), supplementary requirements for U.S. CABs, consultant issues, and scheduling.

February 7, 2000 - FDA and CEC representatives discussed the MRA with consumer representatives at the Transatlantic Consumer Dialogue (TACD) in Washington, D.C.

February 17, 2000 – FDA sent CEC a request for confirmation that confidentiality will be maintained of the material submitted and that only EC Government employees would be used to review US CAB dossiers.

February 28, 2000-FDA and the CEC held the sixth "Stakeholders Meeting" as an audio-conference.

March 1, 2000 – Awaiting confirmation from the CEC that only EC Government employees would be reviewing US CAB dossiers, the FDA re-verified US CAB checklist reference sites and scanned both the checklists and supporting evidence for 8 US

CABs onto CD-ROMs. Two previously designated US CABs have withdrawn from confidence building activities indefinitely.

March 28, 2000 – FDA met with George Willingmyre, GTW Associates, to brief him on the MRA Medical Devices Annex. Mr. Willingmyre is preparing educational materials for EU industry on all sectors of the MRA.

May 22, 2000 – A MRA Joint Committee (JC) meeting was held in Brussels, Belgium. Topics of discussion included the Medical Device Annex and status of confidence building activities.

May 25, 2000 – A meeting with representatives of NIST, ANSI, and RAB was held to discuss what FDA and NIST want ANSI and RAB to do to evaluate US CABs ability to do work for the EC. ANSI and RAB will decide if they are willing to do evaluations.

June 6, 2000 - FDA and the CEC held the seventh “Stakeholders Meeting” as an audio-conference.

June 29 2000 - Pre meeting in Brussels with EU parties to discuss progress prior to a videoconference with the US. Reached agreement on protection of confidentiality in reference to exchange of information from the US CABs. Discussed the progress of the training audit programme.

June 29, 2000 – CEC and FDA held informal meeting (via PictureTel) of Joint Sectoral Committee representatives and staff to discuss progress of MRA.

June 29, 2000 - DOC ITA representative and EC and EUCOMED meet in Brussels to discuss plans to promote the MRA to U.S. and EU SMEs.

July 12, 2000 - Medical devices expert group meeting in Luxembourg with CEC representatives from Member States, industry, interested parties and The Commission. Discussed the Joint Implementation Plan version 7, which was distributed for comments. Brief discussion on the possibility of expanding product coverage IVDs specifically mentioned.

July 18, 2000 - FDA and the CEC held the eighth “Stakeholders Meeting” as an audio-conference.

July 19, 2000 - FDA received EC edits of MRA Draft Implementation Overview and Procedures documents (Version # 7).

September 8, 2000 - FDA received a letter from the CEC confirming that only EC government employees will review US CAB dossiers.

September 11, 2000 - FDA met with representatives of ANSI, RAB, and the US CABs in Milwaukee at RAB headquarters to provide an update on the status of the MRA and discuss the roles of ANSI and RAB in assessing the US CABs.

September 15, 2000 – FDA and CEC representatives discussed the MRA with consumer representatives at the Transatlantic Consumer Dialogue (TACD) in Brussels, Belgium.

September 22, 2000 - FDA and the CEC held the ninth “Stakeholders Meeting” in Ottawa, Canada, during the GHTF Conference, to discuss implementation of the MRA.

October 1, 2000. DOC ITA completes plans to promote the MRA to U.S. firms with seminars in New York on June 6, in Boston on June 7, in San Francisco on June 12 and in Minneapolis on June 14. The full promotion campaign will begin in early March.

October 3, 2000 - FDA published a Federal Register notice announcing the availability of Version # 7 of the MRA Draft Implementation Overview and Procedures documents on the MRA homepage and requested comments by November 2, 2000.

October 3, 2000 - FDA conducted a teleconference with ANSI and NIST representatives to provide an update on the stakeholder meeting held on September 22. FDA requested that ANSI encourage the US CABs to comment on the Draft Implementation Overview and Procedure. ANSI will convey information to US CABs.

October 6, 2000 - FDA sent (via FedEx) checklists and supporting evidence for 8 US CABs to the CEC.

October 20, 2000 – FDA and CEC discussed briefly the Medical Device Annex as part of MRA teleconference.

November 11 2000 - Medical Devices Expert Group meeting in Brussels with CEC representatives from Member States, industry, interested parties and The Commission. Agreed to form a small group to evaluate the designation of US CABs. Nominations requested from Regulatory and Designating Authorities only. Nominations were subsequently received from The Netherlands, United Kingdom, Germany, France and Sweden.

November 18, 2000 – FDA and CEC representatives discussed MRA at Transatlantic Business Dialogue (TABD) in Cincinnati, Ohio.

November 20, 2000 – FDA and CEC discussed MRA briefly at a MRA Joint Committee meeting in Washington, D.C.

December 1, 1999 – December 1, 2000 – FDA conducted seventeen (17) joint quality system audits of EU medical device manufacturers with designated EU CAB auditors.

To date, FDA has completed training of four (4) auditors from four (4) EU CABs in auditing EU medical device manufacturers against FDA requirements.